

## **REMARKS**

In the Final Action dated March 10, 2004, Claims 1, 6-15, 20-26, 28-30, 32 and 34-60 are pending and under consideration. The claims are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

It is observed that the present claims are drawn to compositions comprising leukemia inhibitory factor (LIF) or a derivative or homologue thereof and a stabilizing agent. According to the Examiner, the specification does not provide any specific definition for "leukemia inhibitory factor".

Applicants wish to direct the Examiner's attention to the specification at page 5, line 4, where the specification has referenced International Patent Applications PCT/AU88/00093 and PCT/AU90/00001 for murine and human LIFs.

The Examiner contends that the art recognizes LIF as a synonym for at least nine different factors defined on the basis of their effect on different cell types. The Examiner refers to the abstract of Van Vlasselaer et al. (*Prog. Growth Factor Res.* 1992, vol. 4, 337-353) to support his position.

Applicants respectfully submit, however, that at page 338 of Van Vlasselaer et al., it is stated that "...LIF was found to be identical to several factors that were independently purified and cloned based on activities on a variety of seemingly unrelated cell types and tissues". It is clear from Van Vlasselaer et al., that LIF is not a synonym for at least nine different factors. Rather, LIF is the art recognized term for a single molecule that has previously been known by several different names. The fact that Van Vlasselaer et al. use the term "LIF" in the title and

throughout the article, rather than any of the other names previously used to describe the molecule, acknowledges that LIF was the art recognized term for the molecule in 1992 (five years before the present application was filed). As such, Applicants respectfully submit that the reference to "LIF" in the claims clearly identifies the protein to those skilled in the art.

The Examiner argues that LIF is structurally related to IL-6, OSM, CNTF, IL-11 and CT-1 and has redundant activities with these molecules. Thus, the Examiner is of the opinion that the derivatives, homologues and functional equivalents of LIF, as recited in the claims, would encompass these molecules.

Applicants respectfully disagree with the Examiner. Applicants respectfully submit that a comparison of the sequences of these cytokines (including LIF) shows that they are not all that related. Further, even assuming that these cytokines may be structurally related to each other to some extent, the structural relatedness of these molecules simply means that they all have a similar helical structure. Many proteins have a helical structure. Finally, as noted in the *Cytokine Mini-Review* from the R&D Systems 1999 Catalogue: "...family of molecules that includes LIF, OSM, CNTF, CT-1 and IL-11. Although all molecules possess a similar helical structure, their association is due to their functional redundancy and receptor interactions". It is believed that the functional redundancy arises from receptor components in common, such as the receptor chain gp130, and is not due to any similarities shared by the cytokine molecules themselves.

Therefore, Applicants respectfully submit that the term "LIF", as recited in the present claims, is unambiguous and clearly understood by those skilled in the art. The claimed subject matter relating to stabilized compositions comprising LIF is adequately described in full compliance with the written description requirement under 35 U.S.C. §112, first paragraph.

Therefore, the rejection under 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of the rejection is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'F. DiGiglio'.

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